UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, the **PEOPLE OF THE STATE OF NEW YORK** and the **COUNTY OF ONONDAGA**, ex. rel. **PAUL BLUNDELL,** Relator

Plaintiffs,

v.

DIALYSIS CLINIC, INC.,

Defendant.

JURY TRIAL DEMANDED

AMENDED COMPLAINT
Civ. No. 09-0710 NAM/DEP

AMENDED COMPLAINT FOR DAMAGES AND PENALTIES UNDER FEDERAL FALSE CLAIMS ACT AND THE NEW YORK STATE FALSE CLAIMS ACT

(Filed in-camera pursuant to 31 USC § 3730 (b) (2))

I. INTRODUCTION

1. This is an action under the Federal False Claims Act, 31 USC §§ 3729-3733 and the New York State False Claims Act, Article XIII of the New York State Finance Law. This action is brought on behalf of the United States of America, the People of the State of New York and Onondaga County by a relator. Relator alleges that Dialysis Clinic, Inc. ("DCI") defrauded the United States of America, the State of New York and Onondaga County by presenting claims for payment for dialysis treatment on the basis of false certifications that DCI was in compliance with New York State and federal standards, and on the grounds that the federal, New York State and Onondaga County governments would not have paid DCI's claims for payment had they been aware of the poor quality of care that DCI provided at its University Dialysis Center ("UDC") in Syracuse, New York

and at other facilities. Payment cannot and should not have been legally made by the United States for Medicaid, Medicare and Veterans Administration claims, and by New York State and Onondaga County for treatment that is performed in violation of state and federal standards or for poor quality care. Relator seeks, on behalf of the United States, the imposition of a civil penalty between $5,000.00 and $10,000.00, recovery of three times the amount of damages sustained by the United States, declaratory and injunctive relief, and an award of attorneys' fees. Relator also seeks, on behalf of the people of the State of New York and Onondaga County, the iposition of a civil penalty between $6,000 and $12,000, recovery of three times the amount of damages sustained by New York State and Onondaga County, declaratory and injunctive relief and an award of attorneys' fees.

1a. This Amended Complaint is filed as a matter of course, pursuant to F.R.C.P. Rule 15 (a) (1), because no responsive pleading has been filed to the original Complaint and, in any event, no responsive pleading is allowed until after the Complaint is unsealed, and the Amended Complaint is filed within 20 days of the original Complaint.

II. JURISDICTION AND VENUE

2. This action is specifically authorized by 31 USC § 3730 (b). This court has jurisdiction of this matter pursuant to 31 USC § 3732 and 28 USC § 1331.

2a. The claims under the New York False Claims Act are specifically authorized by § 190 (2) of the New York State Finance Law. These claims "are so related to the claims within" this Court's original jurisdiction over the federal claims to be within the supplemental jurisdiction of this Court pursuant to 28 U.S.C. § 1367.

3. The fraudulent conduct at issue in this proceeding occurred, in part, within the Northern District of New York, and defendant is deemed to be a resident of the Northern District under 28 USC § 1391(c). Venue is therefore appropriate in the Northern District of New York pursuant to 28 USC § 1391(b) and 31 USC § 3732.

III. THE PARTIES

4. Relator Paul Blundell is a citizen of the United States, who resides at 714 Second Street, Liverpool, New York.

5. Relator brings this action on behalf of the United States pursuant to 31 USC § 3730 (b) (1).

5a. Relator brings this action on behalf of the people of the State of New York and Onondaga County pursuant to § 190 (2) of the New York State Finance Law.

6. Defendant Dialysis Clinic, Inc. is a corporation domiciled in Tennessee that is doing business in New York as a foreign not-for-profit corporation.

IV. FACTS

A. Dialysis Clinic, Inc.

7. DCI operates over approximately 200 dialysis treatment centers in the United States, with annual revenue in excess of $500 million. In addition to operating treatment centers for dialysis, DCI also spends tens of millions of dollars on research and education.

8. DCI, since it was established in 1971, has established over 200 outpatient dialysis facilities.

9. According to the Urban Institute National Center for Charitable Statistics, DCI had gross receipts of $545,139,880 in fiscal year 2007, and had total assets of $433,658,041. The Urban Institute also states that, for the fiscal year ending on September 30, 2005, DCI performed 1,795,704 dialysis procedures, generating a total of $338,403,814 in revenue.

10. According to DCI's website, www.dciinc.org, it operates 10 dialysis centers in New York State. UDC was established at some point prior to September 25, 1980, the date that it was first certified for Medicare reimbursement.

11. Dialysis is a method of treating End Stage Renal Disease ("ESRD"). Dialysis treatment, in general, replaces the function of the kidneys, which normally serve as the body's natural filtration system. Through the use of a blood filter and a chemical solution known as dialysate, the treatment removes waste products and excess fluids from the bloodstream, while maintaining the proper chemical balance of the blood.

12. Dialysis treatment, in effect, involves the removal of a patient's blood from his or her body, sending it through an artificial filtration system to clean it, and then returning it to the patient's body.

13. Dialysis treatment, involving the complete recirculation of a patient's blood, is a serious matter, and it is critical to follow proper medical procedure with respect to dialysis.

14. Proper medical procedure with respect to dialysis includes careful monitoring of the operation of the dialysis machine. During the treatment, the machine must be monitored to confirm that blood is flowing properly, that the correct dosage of anticlotting medication, particularly Heparin, is being administered, and that the patient does not exhibit any sign of trouble during the dialysis treatment.

B. Regulation of dialysis facilities

15. Dialysis treatment centers are regulated as "hospitals" pursuant to Article 28 of the New York State Public Health Law (§ 2801 defines hospitals to include treatment centers). Regulations for the operation of treatment facilities are set forth in Title 10 of the New York Codes Rules and Regulations, which sets forth the regulations promulgated by the New York State Department of Health.

16. Dialysis facilities are considered to be treatment or diagnostic centers, within the meaning of 10 NYCRR § 700.2. Treatment and diagnostic centers are regulated pursuant to Chapter 5, Subchapter C, Article 6 of Title 10 of the NYCRR, §§ 750 – 759.

17. 10 NYCRR § 751.5, captioned "Operating Policies and Procedures," requires that the operators of all treatment and diagnostic centers "ensure...the development and implementation of policies and procedures written in accordance with prevailing standards of professional practice...".

18. 10 NYCRR § 757 sets forth requirements for the operation of dialysis facilities. Specifically, 10 NYCRR § 757.1 requires that renal dialysis facilities "comply with the regulations for end-stage renal disease services contained in Title 42 of the Code of Federal Regulations, Public Health, Part 405, Subpart U-Conditions of Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services, (42 CFR Part 405), 1988 edition" (most of Part 405 has been repealed; the amended standards of Part 405 have been recodified in 42 CFR Part 494).

19. Section 757.1 cross-references, and mandates compliance with the requirements set forth in 42 CFR Part 405, as Part 405 was effective in 1988. Section 757.1 (2) – (13) references specific paragraphs of Part 405, including:

¶ (2) Compliance with Federal, State and local laws and regulations (42 CFR § 405.2135)

¶ (5) Patients' rights and responsibilities, (42 CFR § 405.2138)

¶ (6) Medical records (42 CFR § 405.2139)

¶ (7) Physical environment (42 CFR § 405.2140)

¶ (8) Reuse of hemodialyzers and other dialysis supplies (42 CFR § 405.2150)

¶ (11) Staff of a renal dialysis facility or renal dialysis center (42 CFR § 405.2162)

¶ (12) Minimal service requirements for a renal dialysis facility or a renal dialysis center (42 CFR § 405.2163)

20. Furthermore 10 NYCRR § 708.5 (d) (ii) explicitly mandates: "Any facility providing services to ESRD patients must comply with federal regulations for ESRD services."

21. On April 15, 2008, the United States Department of Health and Human Services adopted new rules and conditions for certification of dialysis facilities under the Medicare program. The provisions of these new rules took effect on October 14, 2008 (73 Fed. Reg. 20370). This new rule replaced the former 42 CFR Part 405, Subpart U, with a new 42 CFR Part 494 and added several new sections.

22. The new Part 494, like the former Part 405, requires compliance with standards "to protect dialysis patients' health and safety and to ensure that quality care is furnished to all patients in Medicare approved dialysis facilities" 73 F.R. at 20372.

23. The violations of proper procedures by defendant DCI described at length below occurred prior to the adoption of the new regulations and, upon information and belief, are continuing today after the adoption of the new regulations.

24. In any event, 10 NYCRR § 757.1 still requires compliance with the now superseded Part 405 and a violation of the State regulations still constitutes a false claim pursuant to § 494.5, which requires a Medicare or Medicaid provider to comply with all applicable state standards.

C. DCI's violations of patient safety conditions

25. Relator Paul Blundell, as specified in the attached "Report to the Government," was employed by UDC from August 2007, until October 2008. He worked as a staff nurse and team leader from December 2007 through May 2008, and as charge nurse from May through September 2008.

26. After being demoted from charge nurse to staff nurse in September, Mr. Blundell was terminated on October 6, 2008, allegedly for being rude to a patient.

27. During Mr. Blundell's employment at DCI, he raised a number of questions with respect to patient safety and failure to comply with good nursing practice, and with respect to proper documentation of dialysis treatments. Many of the questions raised implicate billing issues for Medicare, Medicaid and Veterans Administration patients.

28. UDC has approximately 40 employees and performs approximately 300 treatments per week. Each of these treatments is billed at approximately $140 per treatment, for an estimated billing of $42,000 per week, or approximately $2.2 million per year.

29. UDC systematically violated proper procedures and regulatory requirements by failing to provide adequate staffing, permitting medication to be administered by unqualified personnel, permitting contamination of medications and supplies, falsifying medical treatment records, and improperly assessing patients.

30. Furthermore, DCI has severely compromised patient safety, and has also violated New York State law and state and federal regulations, by permitting unqualified employees to perform medical functions.

31. DCI's presentation of claims for payment by the United States represents both a "false certification" that DCI has complied with regulatory criteria and "quality of care" fraud inasmuch as the actions and omissions have placed patients at risk, and, upon information and belief, the United States would not have paid DCI's claims if it was aware of DCI's shortcomings.

1. Inadequate Staff

32. UDC has approximately 30 patient treatment stations. These 30 treatment stations are divided into two pods; one pod has 13 treatment stations and the other has 14 treatment stations, as well as three private treatment areas.

33. Each of the two pods should be staffed by a Registered Nurse ("RN") and a Licensed Practical Nurse ("LPN"), supervising two Personal Care Technicians ("PCTs"). The RN would be specifically responsible for supervising the LPN with respect to a patient who needs a catheter. The LPN would be specifically responsible for supervising the PCTs with respect to patients with fistulas, i.e. patients who have had a vein grafted to an artery to facilitate dialysis treatment.

34. The generally recognized standard of care should be a total staff to patient ratio of 1:3 or, at worst, 1:4. One RN, one LPN and two PCTs (four staff members) caring for 12 patients would meet this standard.

35. According to the schedule that has been promulgated by DCI at UDC, each pod has two LPNs, assisted by two or three PCTs. The LPNs and PCTs are supervised by one charge nurse, who is an RN.

36. In practice, UDC has not even maintained the staffing described in its master schedule. Although one RN has always been present, it is routine for UDC to have only one LPN and three or four PCTs, for all 30 patients. One RN, one LPN, and three or four PCTs (five or six staff members) caring for 30 patients is a ratio of either 1:5 or 1:6.

37. This staffing ratio did not comply with the requirement of § 405.2162 (b) that "an adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of the patients."

38. The new regulation, § 494.180 (b), explicitly mandates that a registered nurse "be present in the facility" whenever dialysis treatment is provided and requires "an adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients; and the registered nurse, social worker and dietician of the interdisciplinary team are available to meet patient clinical needs."

2. Use of unqualified personnel

39. UDC routinely permitted PCTs to perform functions that should properly be performed by LPNs and RNs, including utilizing PCTs to supervise patient treatment, and allowing uncertified PCTs to administer Heparin. LPNs have routinely performed tasks that should properly have been performed by RNs.

40. The use of unqualified personnel violated the regulatory requirement of § 405.2135 (b): "*Standard: licensure or registration of personnel.* Each staff member is currently licensed or registered in accordance with applicable law."

41. The use of unqualified personnel similarly violates § 494.140. "All dialysis facility staff must meet the applicable scope of practice board licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions."

3. Falsification of records

42. One of the critical documents that must be filled out for each patient is a "medical record flowsheet" ("the flowsheet") which documents each dialysis treatment. A sample flowsheet, together with an explanation prepared by Relator describing the systematic types of errors caused by DCI, is annexed to the Report to the Government.

43. DCI routinely directs unqualified personnel to enter information on the flowsheet, backdate information, and simply falsify data.

44. Dialysis utilizes an extensive amount of water, as part of the treatment process.

45. It is essential that the water be checked, to ensure proper flow and cleanliness, before the commencement of dialysis. The fact that the water check was done is also required to be recorded on the water log and verified on the flowsheet.

46. However, at UDC, PCTs failed to conduct the water checks on numerous occasions, and routinely falsified the water logs to indicate that the water checks had actually been done.

47. Prior to each dialysis treatment, the patient should be assessed by an RN. The flowsheets were falsified to indicate that these assessments were done prior to the beginning of dialysis (the assessments themselves are described in ¶¶ 67-68 below).

48. During the course of dialysis treatment, it is also critical that medical personnel regularly check and document the patients' vital signs. These vital signs, including pulse, blood pressure, and blood flow rates, are required to be contemporaneously recorded on the flow sheet.

49. Relator observed that these vital signs were not being recorded in a timely fashion. He brought the issue to the attention of his supervisor.

50. On one occasion, Relator was directed to record vital signs that had been taken at a different time, without identifying the vital signs as a late entry.

51. Although Relator refused to falsify the medical record by recording vital signs that had been taken at some point in the past, a number of PCTs and some of the LPNs frequently falsified the medical records.

52. The preparation of records in this manner obviously violates "accepted professional standards and practices," as expressly required by § 405.2139.

53. DCI's practices blatantly violate § 494.170 which explicitly provide that "the dialysis facility must maintain complete accurate, and accessible records on all patients."

4. Reliance upon PCTs to perform nursing functions

54. In addition to not providing an adequate number of total staff, UDC does not staff the facility with a sufficient number of properly licensed nurses.

55. UDC's understaffing has meant the PCTs have routinely performed work, including assessment of patients and the administration of medications, that should properly have been performed by nurses.

5. Administration of Heparin

56. Successful dialysis requires the administration of an anticlotting drug. Typically, and at UDC, Heparin is utilized.

57. In conversations with Relator, DCI management claimed that the New York State Department of Health had permitted certified PCTs to prime the dialysis machine with Heparin, while the machine is not attached to a patient.

58. PCTs at UDC customarily primed the machine, even though none of them have been certified.

59. Of even greater importance, PCTs, even if certified, are not permitted to administer Heparin while a patient is attached to the machine. The administration of Heparin would constitute the practice of nursing, and the practice of nursing by unlicensed persons is prohibited by state law (Education Law § 6903).

60. UDC has routinely permitted, if not directed, PCTs to administer Heparin to patients. The use of PCTs to administer Heparin is necessary because DCI has failed to staff the UDC facility with a sufficient number of LPNs. One, or even two, LPNs can not handle the administration of Heparin to all 30 patients.

61. Furthermore, UDC has also routinely violated New York State Department of Health directives with respect to the management of Heparin. Heparin is supposed to be prepared in the medical room, which should be kept as a clean environment. Nevertheless, the staff of UDC regularly brings Heparin out onto the floor, in contact

with the patient treatment areas, thus contaminating it before returning it to the clean medical room.

62. Similarly, PCTs commonly place unused syringes back into the clean medical room, thereby contaminating the clean and unused syringes.

6. Assessment of patients

63. The RN is responsible for assessing each patient prior to the beginning of each dialysis treatment, to ensure that a patient does not have any disqualifying conditions which would contraindicate treatment on a particular occasion.

64. The New York State Nurse Practice Act defines "the practice of the profession of nursing as a registered professional nurse" to include "diagnosis and treating human responses to actual or potential health problems." In contrast, "the practice of nursing as a licensed practical nurse is defined as performing tasks and responsibilities…under the direction of a registered professional nurse or licensed physician…" (Education Law § 6902).

65. An LPN or a PCT is not legally authorized to assess a patient's condition pursuant to the New York State Nurse Practice Act.

66. The flowsheet has a section pertaining to the assessment of the patient. Assessment of patients can only be performed by RNs, Nurse Practitioners, Physicians' Assistants and Medical Doctors.

67. The assessments to be recorded on the flowsheet include a lung sound assessment, verification of medication, and general assessment of the patient's condition prior to the beginning of dialysis. It is both required by law and necessary for the safety of the patient that such an assessment be performed by a duly qualified nurse. Further, this assessment is required prior to the initiation of treatment.

68. Some dialysis patients have "fistulas," grafts of a vein onto an artery that have been surgically implanted to facilitate dialysis treatment. A Registered Nurse, as part of the pre-dialysis assessment, should palpate and ausculate each fistula site and record the results. Although this was not done at UDC due to the scarcity of RN's, PCTs and LPNs recorded that the assessment had been performed by RNs.

7. Verification of medication

69. It is critical that prescription medication for a dialysis patient be verified by an LPN, prior to the commencement of dialysis treatment. The failure to do so is itself a serious violation of medical procedures and of safe nursing practice.

70. However, at UDC, the verification of prescription medication is routinely performed by PCTs, rather than LPNs or RN's.

71. Here, the problem is complicated by the fact that not only is the prescription not properly verified by an LPN, the record is then falsified by PCTs to indicate that it had been verified by a specially trained LPN or RN.

72. Relator reported numerous instances to his supervisors, both verbally and by e-mail, of cases where prescriptions were not verified prior to the commencement of treatment. Nevertheless, management ignored the concerns, and did not take any action to remedy the continuing failures to verify prescriptions.

8. Home Dialysis

73. UDC offers home dialysis. New York State requires that every renal dialysis facility outside of New York City "work toward a goal of at least 15 percent of its patients on home dialysis." (10 NYCRR § 708.5 (d)).

74. Relator, as a charge nurse, is aware of instances where home dialysis treatment has failed due to the lack of appropriate supervision.

75. There were occasions when the home dialysis RN was not present in the building, and the RN charge nurse for the facility, in addition to his or her other duties, was required to administer and distribute medications. This was especially problematic because the RN charge nurse did not regularly monitor the home dialysis patients and was not familiar with their particular situations and medical needs.

76. § 405.2163 (a) (1) stated: "*Standard: Outpatient dialysis services- (1) Staff-assisted dialysis services.* The facility must provide all necessary institutional dialysis services and staff required in performing the dialysis." § 494.100 requires that "a dialysis facility that is certified to provide services to home patients must ensure through its interdisciplinary team, that home dialysis services are at least equivalent to those provided to in-facility patient and meet all applicable conditions of this part," and sets forth specific requirements for the training of the patient, monitoring of treatment and record keeping.

9. Infection control

77. While Relator was employed at UDC, UDC engaged in a number of practices that were unsafe. Specifically:

a) medications were drawn up on the treatment floor, rather than in a clean environment,

b) medications that were drawn up on the floor were then returned to a clean environment, thereby contaminating the clean environment, and

c) the management team refused to sterilize treatment trays between their use for different patients.

78. The actions of UDC did not comply with the then existing standard contained in § 405.2140 (c), which requires a facility to "employ appropriate techniques to prevent cross-contamination between the unit and adjacent hospital or public areas." The new § 494 sets forth specific requirements to insure that a "dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas." (§ 494.30).

10. Heating and ventilation systems

79. Patients receiving dialysis are susceptible to cold, inasmuch as their blood is being recirculated through a machine, and it is sometimes difficult for them to stay warm.

80. At UDC, patients frequently complained about the cold temperatures. The problem was exacerbated because the HVAC system had vents immediately over the patient care areas, which blow directly onto the patients. Management ignored repeated recommendations, both from Relator and from others, to relocate these vents.

81. UDC supplied blankets to some patients who were cold. However, UDC did not have enough blankets for all patients who requested them. Nursing staff attempted to compensate by offering gowns that provided much less insulation and warmth.

82. UDC violated § 405.2140 (b) (2) which required that treatment areas be designed for the "comfort" of the patients, and (b) (4) which required that "heating and ventilation systems are capable of maintaining adequate and comfortable temperatures." These requirements are now contained in § 494.60 (c) (2) which requires a dialysis facility to "maintain a comfortable temperature within the facility and make reasonable accommodations for the patients who are not comfortable at this temperature."

11. Adequate surveillance

83. UDC maintains two pods, plus separate treatment areas for isolation. All of these areas are supervised by, at most, one RN. If, as has happened on occasion, the RN walked into one pod, the nurse can not observe patients in the other pod and isolation areas.

84. § 405.2140 (b) (3) required that "there is a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made." § 494.60 (c) (4) provides "patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement)."

12. Emergency preparedness

85. UDC routinely failed to check the readiness of the automated external defibrillator. Furthermore, on many occasions, the log was backdated and falsified, indicating that it had been checked, even though it had not been checked.

86. Furthermore, the "crash cart," which contains emergency supplies to assist patients who undergo crises during dialysis, was not checked daily by an RN or an LPN. The logbook was frequently left blank for several days at a time, indicating that no one had verified that the crash cart was functional.

87. Relator believes that the logbook was subsequently completed several days later, to falsely indicate that the daily checks had actually been performed.

88. No training (other than CPR) was provided to employees, including Relator and other nursing professionals, with respect to responding to emergency situations.

89. In relevant part, § 405.2140 (c) provided: "All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster…There is available at all times on the premises a fully equipped emergency tray,

including emergency drugs, medical supplies, and equipment, and staff are trained in its use."

90. § 494.60 (d) specifically requires "The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following:…Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs…Emergency equipment, including but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available."

13. Patients' rights

91. UDC did not provide patients with access to the 800 numbers that are available to file either internal grievances or to file an external grievances with governmental authorities. Furthermore, the notification with respect to patients' privacy rights under HIPPA was only displayed in the lunchroom, where it could not be seen by patients.

92. UDC's practices violated the standard contained in § 405.2138 (e), which required a facility to "encourage and assist" patients to understand and exercise their rights. § 494.70 (a) specifically requires that a facility inform a patient about both the internal and external grievance processes, and requires that the facility prominently display a copy of the patients' rights in a location where it can easily be seen and read by patients.

14. Falsification of assessment records

93. On at least one occasion, UDC admitted a patient without completing an assessment form within the first 45 days. The assessment form was later found to have been falsified by the patient's sister, who had pretended to be the child's mother and had filed and signed

the intake forms as his mother. Upon learning of this learning of this falsification, the management team determined to shred the paperwork, and substituted a backdated intake form, signed by the patient's real mother.

94. § 494.80 (b) specifically requires that an initial comprehensive assessment must be conducted within 30 days or 13 outpatient hemodialysis sessions of the first session. Although Part 405 did not specifically set a requirement for the initial assessment, the delay of assessments until more than 45 days after a patient's initial session violates any reasonable quality of care standard.

15. Interdisciplinary meetings

95. UDC does not permit staff or charge registered nurses to participate in interdisciplinary meetings. Therefore, the only registered nurses who participate in the interdisciplinary meetings are management employees who are not involved in the daily dialysis of the patient.

96. § 405.2137 (b) required that a dialysis facility prepare a written patient care plan for each patient, and further required that the plan be developed by a professional team which includes "a qualified nurse responsible for nursing services" (§ 405.2137 (b) (2)).

97. Part 494 contains specific requirements for the development and implementation of the patient care plan by the interdisciplinary team (§ 494.90), and that a registered nurse be a member of this team (§ 494.80).

16. Untrained Patient Care Technicians

98. As noted above, UDC relies upon PCTs to perform functions that should properly be performed by LPNs and RNs. PCTs perform assessments, administer medication, and perform other nursing functions.

99. However, during the time that Relator was employed at UDC, PCTs employed by UDC did not receive any formal training, other than on-the-job training. Upon information and belief, PCTs employed by UDC are not certified by any organization.

100. Although Part 405 did not have any formal requirements for training PCTs, upon information and belief, some formal training is necessary to assure proper quality of care to dialysis patients. This is especially true in facilities such as UDC, where PCTs perform a number of specialized functions that they should not be performing.

101. Significantly, § 494.140 (e) now requires that PCTs, in addition to having a high school diploma, must complete a training program including the principles of dialysis, care of patients with kidney failure, analysis procedures and documentation, possible complications of dialysis, water treatment and dialysis preparation, infection control and safety.

17. Training requirements for nurses

102. It is obviously important that a charge nurse in a dialysis facility have the requisite amount of experience.

103. Nevertheless, UDC regularly appointed nurses with inadequate or little experience in dialysis to the position of charge nurse.

104. Relator was appointed to the position of charge nurse after three months of orientation and four months of actual care experience. In September 2008, UDC appointed Andrew Jones to the position of charge nurse, despite the fact that he had minimal relevant dialysis experience.

105. Inasmuch as the charge nurse has a variety of responsibilities, from the direct oversight of the of LPN's and PCTs providing dialysis, to the handling of emergencies, the

administration of medication, and the assessment of patients, including the physical evaluation of patients, it is essential that the charge nurse have adequate training.

106. § 405.2102 (d) required that a "nurse responsible for nursing service" have at least 12 months of experience in clinical nursing and an additional six months of experience in nursing care of a patient with permanent kidney failure, including training in the dialysis process.

107. Under § 494.140 (b) (3), this requirement was weakened, to only require a charge nurse to have a total of 12 months experience, with three months of experience in providing nursing care to patients on maintenance dialysis.

108. However, the applicable New York State regulation, which is still in effect, requires a dialysis facility to have an RN on staff who:

> (1) has at least 12 months of experience in clinical nursing and an additional six months of experience in nursing care of patients with permanent kidney failure or who are undergoing or have undergone kidney transplantation, including training in and experience with the dialysis process; or
> (2) has at least 18 months of experience in nursing care of patients on maintenance dialysis or in nursing care of patients with kidney transplant, including training and experience with the dialysis process.
> (10 NYCRR 708.5 (d) (xiv) (a))

18. Summary

109. In summary, UDC systematically violated proper medical procedures, New York State requirements for limiting the practice of nursing to registered and licensed nurses, and also engaged in a variety of basically unsafe practices.

110. Most of these practices were the result of inadequate staffing; because DCI refused to provide an adequate number of RNs and LPNs, and permitted PCTs to perform the work of the LPNs and RNs, and LPNs to perform the work of RNs.

111. As a result, patients were placed at risk because of the lack of proper staffing, medical records were falsified, and patients were subjected to the risk of having their dialysis treatment compromised by exposure to contaminated medical supplies.

D. Fraudulent health care claims under federal programs

112. Medicaid and Medicare are "Federal Health Care Programs" as that term is defined by 42 USC § 1320a-7b (f).

113. Medicaid is a program that provides assistance for medical expenses incurred by individuals without adequate resources to pay for medical care. The Medicaid program is administered by New York State and local governments, pursuant to Title 11 of Article 5 of the New York State Social Services Law. Fifty percent of the cost of the Medicaid program is paid by the United States of America, pursuant to Title XIX of the Federal Social Security Act, 42 USC § 1396 et seq. The other fifty percent of the cost of the Medicaid program is paid by the state and local social service districts (see New York State Social Services Law, § 368-a)

114. Medicare is a federally funded program established pursuant to Title XVIII of the federal Social Security Act, 42 USC § 1395 et seq. that pays for medical benefits for individuals over the age of sixty-five years and for individuals who are disabled.

115. The Veterans Administration also pays health care providers to provide medical services for individuals, principally veterans, when services can not be provided at Veterans Administration facilities.

116. In United States ex. rel. Mikes v. Straus et al., 274 F. 3d 687, 69 (2d Cir. 2001), the Second Circuit held that a claim for Medicare reimbursement "is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment."

117. The Ninth Circuit recently noted: "Many different courts have held that a claim under the False Claims Act can be false where a party merely falsely certifies compliance with a statute or regulation as a condition to government payment." United States ex. rel. Hendow v. University of Phoenix, 461 F.3d 1166, 1171 (9th Cir. 2006). Hendow cited the four criteria set forth in United States ex. rel. Hopper v. Anton, 91 F.3d 1261 (9th Cir 1996) for false certification claims: 1) the claim must be false, 2) the claimant must know that the claim is false, 3) the false statement must be material to the decision to pay monies to the claimant, and 4) the statement must pertain to an actual claim.

118. DCI's claims for payment for dialysis performed at UDC under the Medicare, Medicaid and Veterans Administration programs are false claims because: 1)DCI is falsely certifying that it is in compliance with the applicable regulations for dialysis facilities and 2) DCI knows the United States would not pay these claims if it was aware of the poor quality of care that DCI is providing to patients.

119. Federal regulations explicitly require compliance with the criteria formerly set forth in Part 405 and now set forth in Part 494 as a precondition for the payment of Medicare claims (former § 405.2180 now 42 CFR § 488.604 and 606). Compliance with these criteria is also a prerequisite for the payment of other federal claims, including claims under Medicaid and Veterans Administration programs.

V. AS AND FOR A FIRST CAUSE OF ACTION (Medicaid Fraud)

120. Relator repeats all of the above allegations, with the same force and effect as if set forth in full herein.

121. Title XIX of the Social Security Act, 42 USC § 1396 et seq., provides for federal assistance to states that have established medical assistance programs for the needy that meet the requirements of federal law.

122. The New York State Legislature has stated: "medical assistance for needy persons is hereby declared to be a matter of public concern and a necessity in promoting the public health and welfare and for promoting the state's goal of making available to everyone, regardless of race, age, national origin or economic standing, uniform high-quality medical care. In furtherance of such goal, a comprehensive program of medical assistance for needy persons is hereby established..." New York State Social Services Law, § 363 (see ¶ 113 above).

123. The New York State plan has been approved by the United States Department of Health and Human Services to receive reimbursement for medical expenditures for eligible persons in accordance with Title XIX of the Social Security Act (42 USC §1395 et seq.).

124. The federal government reimburses fifty percent (50%) of the expenses that are paid by the State of New York and local social service districts.

125. 18 NYCRR § 500.1 (a) defines "medical care" under New York State's Medicaid program as "the care, services and supplies enumerated therein, together with any other care, services or supplies authorized to be provided by these regulations and furnished in

accordance with these regulations, sound medical practice and the rules and regulations of the state board or body supervising the respective professions."

126. The medical assistance provided under New York State's Medicaid program is limited to "medical care services and supplies which are medically necessary and appropriate, consistent with quality care and generally accepted professional standards." (18 NYCRR 500.1 (b)) (emphasis added). As described above, the dialysis services that UDC provides do not comply with the standards of quality care and/or generally accepted professional standards.

127. Furthermore, the dialysis care UDC provides does not comply with the specific standards of 10 NYCRR § 757.1, which incorporates, by reference, the relevant standards imposed by the Medicare regulations pertaining to dialysis services (see ¶ 19 above). New York State regulations explicitly require compliance with federal regulations for end-stage renal disease services (see ¶20 above, citing 10 NYCRR § 708.5). The New York State Medicaid program requires that providers of ESRD services comply with the federal standards for Medicare providers, set forth in the former 42 CFR Part 405 and in the current 42 CFR Part 494.

128. Upon information and belief, New York State and Onondaga County (the local social service district for the UDC facility) have paid millions of dollars of claims submitted by DCI for services at its UDC facility in the six years prior to the commencement of this lawsuit.

129. Upon information and belief, the federal government has reimbursed the State of New York for 50% of the payments that it made to DCI for services rendered at its UDC

facility for patients who participated or are participating in New York State's Medicaid program.

130. Therefore, DCI's requests for payment for services from New York State for Medicaid patients are also claims for payment from the United States of America.

131. Because DCI's claims for payment are based upon false certifications that the UDC facility is in compliance with the applicable rules and regulations and of generally accepted practices for quality of care, DCI's claims for payment are false claims within the meaning of the federal False Claims Act, 31 U.S.C. § 3729 et seq..

132. Furthermore, the services rendered at UDC were of low quality care and constituted a significant danger to patients undergoing dialysis treatment.

133. DCI knew, or should have known, that the United States of America would not pay for such services under the Medicaid program, if it had been aware of the poor quality of treatment and of the risks to patients.

134. The United States of America has paid money, pursuant to Article XIX of the federal Social Security Act, to pay "claims" that were submitted by DCI to New York State.

135. Such claims were submitted with the specific intention of having a claim for Medicaid expenses "paid or approved" by the United States of America (31 USC § 3729 (a) (2)).

136. DCI obtained funds under the Medicaid program, which were ultimately paid by the United States of America, based upon its false claims.

137. Upon information and belief, the receipt of funds for Medicaid reimbursement as a result of a false claim constitutes a violation of 31 USC § 3729.

138. The United States of America has sustained damages, in an as yet undetermined amount, as a result of DCI's violations of 31 USC § 3729.

VI. AS AND FOR A SECOND CAUSE OF ACTION (Medicare Fraud)

139. Relator repeats all of the above allegations, with the same force and effect as if set forth in full herein.

140. Title XVIII of the Federal Social Security Act (42 USC § 1395 et seq., commonly referred to as the Medicare Statute) establishes a federal program of health insurance for "aged and disabled" individuals.

141. Under Medicare, medical providers, including renal dialysis facilities such as DCI, submit claims for reimbursement of payment for medical services provided to eligible patients directly to the federal government.

142. § 405.218, which was in effect until October 2008, specified that "failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in this Subpart U will result in termination of Medicare coverage of the services furnished by that supplier."

143. § 405.2180 has now been replaced by 42 CFR § 488.604 which similarly provides that "failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in Part 494 of this chapter will result in termination of Medicare coverage of the services furnished by the supplier."

144. As set forth at length above, the UDC facility owned and operated by DCI has failed to meet a number of the standards for Medicare coverage set forth Part 405 and in Part 494.

145. Consequently, the claims for payment that had been submitted by DCI for services rendered at UDC represent reimbursement payments for services to which DCI was not entitled.

146. DCI submitted claims for Medicare payments for services that were not rendered in compliance with the requirements of federal regulations pertaining to ESRD services.

147. Furthermore, the services rendered at UDC were of low quality care and constituted a significant danger to patients undergoing dialysis treatment.

148. DCI knew, or should have known, that the United States of America would not pay for such services under the Medicare program, if it had been aware of the poor quality of treatment and of the risks to patients.

149. Consequently, DCI has submitted claims for Medicare payment to which it was not entitled.

150. Request for payment of medical expenses under Medicare constitutes a "claim" within the meaning of the Federal False Claims Act, 31 USC § 3729 et seq.

151. DCI submitted claims for payment of expenses under Medicare with the specific intention of having such claims "paid or approved" by the United States of America (31 § USC 3729 (a) (2)).

152. DCI obtained funds under the Medicare program from the United States of America based upon its false claims.

153. Upon information and belief, the receipt of funds for Medicaid reimbursement as a result of a false claim constitutes a violation of 31 USC § 3729.

154. The United States of America has sustained damages, in an as yet undetermined amount, as a result of DCI violations of 31 USC § 3729.

VII. AS AND FOR A THIRD CAUSE OF ACTION (Fraud against the Veterans Administration)

155. Relator repeats all of the above allegations, with the same force and effect as if set forth in full herein.

156. Chapter 17 of Title 38 of the United States Code establishes a program to provide medical treatment for veterans of the United States armed forces.

157. 38 U.S.C. § 1703 authorizes the Veterans Administration to permit veterans to obtain medical treatment at non-Veterans Administration facilities, in cases where it is not feasible to provide the necessary treatment at a Veterans Administration facility.

158. Upon information and belief, the Veterans Administration does not maintain any facilities that provide dialysis within a reasonable proximity to Syracuse, New York.

159. Therefore, DCI has provided dialysis services to veterans at its UDC facility, and DCI has submitted claims for payment for such services to the Veterans Administration.

160. Payment for medical care by the Veterans Administration "shall be based on a prospective payment system similar to that used in the Medicare program for paying for similar inpatient hospital services in the community," 38 CFR § 17.55.

161. Upon information and belief, the Veterans Administration would not have paid DCI's claims, had it been aware of the violations of state and federal regulations, including violations of the Medicare regulations for ESRD treatment, the low quality of care provided at the UDC facility, and of the significant risks to patient health which were created by UDC practices and non-compliances with regulatory criteria.

162. Requests for payment for medical expenses under Veterans Administration constitute "claims" within the meaning of the Federal False Claims Act, 31 USC § 3729 et seq.

163. DCI submitted claims for payment of expenses under Veterans Administration with the specific intention of having such claims "paid or approved" by the United States of America (31 § USC 3729 (a) (2)).

164. Because DCI falsely certified that it was in compliance with regulatory standards and provided good quality care, DCI's claims were "false" within the meaning of the Federal False Claims Act, 31 USC § 3729 et seq.

165. DCI obtained funds from the Veterans Administration of the United States of America based upon its false claims.

166. Upon information and belief, the receipt of funds from the Veterans Administration as a result of a false claim constitutes a violation of 31 USC § 3729.

167. The United States of America has sustained damages, in an as yet undetermined amount, as a result of DCI violations of 31 USC § 3729.

VIII. AS AND FOR A THIRD CAUSE OF ACTION (Medicaid Fraud against the State of New York and Onondaga County)

168. Relator repeats all of the above allegations, with the same force and effect as if set forth in full herein.

169. As described in paragraphs 121 through 128 above, New York State and Onondaga County have paid millions of dollars in claims submitted by DCI for services at its UDC facility under the Medicaid program.

170. Only fifty percent (50%) of the expenses for these claims were reimbursed by the federal government. The remaining fifty percent (50%) was paid by New York State and Onondaga County.

171. As set forth in ¶¶ 130 - 133 above, DCI's request for payment for services from New York State for Medicaid patients were fraudulent, because DCI knew, or should have known, that New York State would not pay for such services if it had been aware of the

poor quality of treatment, the risks to patients, and the failure of DCI to comply with applicable rules and regulations and generally accepted practices for the quality of care.

172. § 189 of the New York State Finance Law imposes liability upon any "person" (defined by § 188 (6) to include "corporations, associations or any other legal entity") who "knowingly presents... a false or fraudulent claim for payment or approval;... a false record or statement to get a false or fraudulent claim paid or approved by the state or local government; conspires to defraud the state or local government by getting a false or fraudulent claim allowed or paid..." (§ 189 (1) (a)-(c)).

173. Upon information and belief, DCI's receipt of funds for Medicaid patients from New York State and Onondaga County constitutes a violation of § 189 of the New York State Finance Law.

174. The people of the State of New York and Onondaga County have sustained damages, in an as yet undetermined amount, as a result of DCI's violations of § 189 of the New York State Finance Law.

RELIEF

WHEREFORE, Plaintiffs United States of America, People of the State of New York and the County of Onondaga, by Relator Paul Blundell, demands judgment against Defendants as follows.

1. An award of money, in an amount presently indeterminable, for violations of 31 USC § 3729 (a), duly trebled,
2. An award of money, in an amount presently indeterminable, for violations of § 189 of the New York State Finance Law, duly trebled,

3. The imposition of a civil penalty, payable to the United States Government, in an amount of not less than $5,000.00, and not more than $10,000.00.
4. The imposition of a civil penalty, payable to the State of New York, in an amount of not less than $6,000.00, and not more than $12,000.00.
5. An award to Plaintiff of his costs and reasonable attorneys' fees.
6. Declaratory and injunctive relief against further fraudulent practices of Defendant.
7. Such other and further relief as to the Court may seem just, proper and equitable.

Dated: July 10, 2009
Clarksville, New York

Peter Henner
Attorney for Relator
Paul Blundell
Federal Bar Roll No. 101956
P.O. Box 326
Clarksville, NY 12041
Tel: (518) 768-8232
Fax: (518) 768-8235